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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,801	09/19/2001	Rajneesh Taneja	6842.US.O1	1051

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,801

Applicant(s)

TANEJA ET AL.

Examiner

Humera N. Sheikh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

James M. Spear
JAMES M. SPEAR
PRIMARY EXAMINER
Au 1615

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/8/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the request for extension of time (2 months-granted) filed 06/02/03 and the Information Disclosure Statement (IDS) filed 03/14/03 is acknowledged.

Claims 1-21 are pending. Claims 1-21 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 14, 15, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 747,293.

GB '293 discloses a pharmaceutical composition comprising a therapeutically effective amount of an acid-labile compound (erythromycin) in combination with acid neutralizers and buffers (see reference column 1, line 14 – col. 3, line 6).

Suitable, physiologically acceptable acid neutralizers disclosed are *aluminum hydroxide*, calcium hydroxide, sodium acetate, magnesium trisilicate, sodium phosphate, *calcium carbonate*, *sodium bicarbonate* and *sodium carbonate* (col. 2, lines 78-85). The acid neutralizers (buffers)

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may be used alone or in suitable combinations (col. 3, lines 4-6). The composition provides for adequate blood levels, whereby pH levels are effectively maintained.

Claims 1, 5, 6 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kouchiwa *et al.* (EP 0 264 259).

Kouchiwa *et al.* disclose stabilized, therapeutic pharmaceutical compositions comprising an active ingredient (dihydropyridines) in combination with one or more of *sodium carbonate*, sodium hydrogen carbonate, *calcium carbonate* and calcium hydrogen phosphate (see reference page 2, lines 1-32 and Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phillips (US Pat. No. 5,840,737) in view of GB 747,293.

Phillips ('737) teaches a pharmaceutical composition and methods for treating and/or preventing gastrointestinal conditions comprising active ingredients of acid-labile compounds (*i.e.*, omeprazole, lansoprazole and derivatives thereof) and a bicarbonate salt of a Group IA metal, preferably sodium bicarbonate (see reference column 7, line 3 – col. 8, line 46); Abstract & Claims.

The composition is used for the treatment of gastrointestinal conditions, including duodenal ulcers, gastric ulcers, gastroesophageal reflux disease (GERD), erosive esophagitis, and the like (col. 8, lines 47-61).

According to Phillips, the sodium bicarbonate acts as an antacid and protects the acid-labile compound (*i.e.*, omeprazole) from acid degradation (col. 8, lines 34-37).

Phillips teaches a water-soluble acid neutralizer – sodium bicarbonate. Phillips does not teach a water-insoluble acid neutralizer, such as a carbonate or hydroxide.

The **GB '293** reference teaches a pharmaceutical, therapeutic composition, based on an acid-labile compound (erythromycin) wherein the composition comprises both water-soluble and water-insoluble acid neutralizers or buffers. Suitable acid neutralizers taught include, for example, *aluminum hydroxide*, calcium hydroxide, sodium acetate, magnesium trisilicate, sodium phosphate, *calcium carbonate*, *sodium bicarbonate* and *sodium carbonate* (col. 2, lines 78-85). The composition provides for adequate blood levels, whereby pH levels are effectively maintained through the use of the acid neutralizers.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the water-soluble and water-insoluble acid neutralizers taught by the GB '293 reference into the acid-labile formulation of Phillips because the GB'293 explicitly teaches acid neutralizers, which function to maintain pH levels within the body and further teaches the employment of acid neutralizers or buffers (i.e., *aluminum hydroxide, calcium carbonate, sodium bicarbonate & sodium carbonate, etc.*) in acid labile formulations. Similarly, Phillips teaches acid labile formulations for gastric acid disorders that contain water-soluble acid neutralizers (i.e., *sodium bicarbonate*), which function as an antacid that protects the acid labile active compound. The expected result would be an improved and stabilized therapeutically effective acid labile formulation that maintains gastric pH levels and prevents degradation of acid labile drugs, as similarly desired by Applicant.

The prior art made of record and not relied upon is considered pertinent to applicant's

disclosure:

US Patent No. 4,786,505 (Lovgren et al.) 11-1988

US Patent No. 6,544,556 B1 (Chen et al.) 08-2003

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh 

Patent Examiner

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December 08, 2004



JAMES M. SPEAR
PRIMARY EXAMINER

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